K123721

JUL 2 6 2013

510(k) Summary

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Date Prepared: November 20, 2012

DEVICE INFORMATION

Trade/Proprietary Name: GMK Revision extension
Common Name: Total Knee Prosthesis
Classification Name: Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/Metal/Polymer

21 CFR 888.3560
Class II
Device Product Codes: JWH

Predicate Devices:
K090988 GMK Total Knee System (Medacta International)
K102437 GMK Total Knee System - Revision (Medacta International)
K120790 GMK Line Extension (Medacta International)

Product Description

The GMK Revision extension is comprised of tibial trays and tibial augments that can be used in either a Primary or Revision surgery. The only difference between the tibial trays and the tibial trays of the predicate device (K090988) is the addition of four threaded screw holes in the bottom surface to allow the connection with the tibial augments. The tibial trays are equivalent to the predicate device (K090988) in terms of material, sizes, general design features and manufacturing process. The tibial trays are offered in six sizes (1 thru 6) in left and right configuration and are made of Cobalt-Chromium-Molybdenum alloy according to ISO 5832-4:1996. The tibial augments are offered in the same seven different sizes (0 thru 6), and 5mm or 10mm thicknesses as the predicate device (K102437) and have a similar shape. They are made of High Nitrogen Stainless Steel M30NW ISO 5832-9. The tibial augments are secured to the tibial trays with either 5mm or 10mm screws made of titanium alloy (Ti6-Al4-V) according to ISO 5832-3:1996.

Indications for Use

The Evolis®/GMK® knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial wedges cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

The screwed tibial augments are for screwed fixation to the tibial baseplate.

In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

In case a GMK Revision tibial tray is used, an extension stem must be implanted.

Comparison to Predicate Devices

The indications for use of the GMK Revision extension are similar to the previously cleared predicate devices. The only difference is that the tibial wedges (augments) from the predicate device (K102437) must be cemented to the tibial baseplate whereas the

tibial augments that are the subject of this submission are screwed to the tibial baseplate. Also, it is specified that an extension stem must be used with the tibial trays that are the subject of this submission. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the GMK Revision extension are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification. The only difference between the tibial trays and the tibial trays of the predicate device (K090988) is the addition of four threaded screw holes in the bottom surface to allow the connection with the tibial augments. The difference between the tibial augments and the tibial augments of the predicate device (K102437) is the material, High Nitrogen Stainless Steel M30NW ISO 5832-9, as compared to Ti6-Al4-V ISO 5832-3:1996 for the predicate device (K102437). In addition, the 5mm or 10mm screws made of Ti6-Al4-V ISO 5832-3:1996 were not present in the predicate device (K102437). The final difference is that the tibial augments do not need to be cemented to the tibial tray as they use screws instead. However, both the tibial augments from this submission and the predicate device (K102437) use cement to secure the augments to the bone.

Performance Testing

Testing was performed according to ASTM F1800 - 07 Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements analyzing the GMK Revision extension components to the worst case of the predicate devices. This analysis determined that the GMK Revision extension is not worst case compared to the predicate devices.

The modification to the GMK system to include the addition of the GMK Revision extension was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The testing was conducted on the worst case component size and option/design based on engineering analysis.

A review of the mechanical data indicates that the GMK Revision extension is equivalent to devices currently cleared for use and is capable of withstanding expected in vivo loading without failure.

Conclusion:
Based on the above information, the GMK Revision extension can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Medacta International SA
% Medacta United States of America
Mr. Adam Gross
Director of Regulatory and Quality
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K123721
Trade/Device Name: GMK Revision extension
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: June 24, 2013
Received: June 25, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123721

Device Name: GMK Revision extension

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Prescription Use ____x____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D

Division of Orthopedic Devices